FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1451–1500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*
WASHINGTON, D. C., *January 24, 1946.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1451. Misbranding of Bristol's Compound and Kemp's Vermifuge (liquid). U. S. v. 153 Dozen Packages of Bristol's Compound and 289 Dozen Packages of Kemp's Vermifuge (Liquid). Default decree of forfeiture and destruction. (F. D. C. No. 14428. Sample Nos. 33165–F, 33169–F.)

On November 14, 1944, the United States attorney for the District of Puerto Rico filed a libel against 153 dozen packages of Bristol's Compound and 289 dozen packages of Kemp's Vermifuge (liquid) at San Juan, P. R., alleging that the articles had been shipped between the approximate dates of March 14 and October 23, 1944, from New York, N. Y., by Lanman and Kemp-Barclay and Co., Inc.

Examination of the Bristol's Compound showed that it contained extracts of plant drugs, including a laxative plant drug such as senna, and an iodide such as potassium iodide. It was alleged to be misbranded in that its labeling failed to warn that the article should not be used in cases of abdominal pain, nausea, vomiting, or other symptoms of appendicitis, and that frequent or continued use of the article or use in accordance with the directions, namely, "For adults, one tablespoonful * * * three times daily * * * For children 3 to 5 years old, ½ teaspoonful; 6 to 11 years, 1 teaspoonful; 12 to 15 years, 2 teaspoonfuls; 16 to 18 years, 3 teaspoonfuls * * * three times daily," might result in dependence upon laxatives to move the bowels. It was alleged to be misbranded

* For drugs actionable because of failure to bear adequate directions or warning statements, see No. 1451; omission of, or unsatisfactory, ingredients statements, Nos. 1470, 1485, 1494; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1481; failure to bear an accurate statement of the quantity of the contents, No. 1492; cosmetics, subject to the drug provisions of the Act, Nos. 1491, 1492.

further in that the statement on its labels, "indicated in the treatment of skin eruptions resulting from faulty elimination," was misleading since a purchaser had no way of knowing whether skin eruptions were due to faulty elimination or to some other condition.

The Kemp's Vermifuge (liquid) was labeled in part: "Formula per 100 c. c.—Active Ingredients: Oil chenopodium 3.40 c. c., castor oil 82.80 c. c., and the matter extracted from: pomagranate bark 2.80 gms., spigelia root 1.80 gms., senna leaves 1.10 gms. * * * Dose: Children 1 to 2 years, 30 Drops (1.20 cc.) Children 2 to 5 years, 1 Teaspoonful 4 c. c. Children 5 to 8 years, 2 Teaspoonfuls 8 c. c. Children 8 to 12 years, 3 Teaspoonfuls 12 c. c. Adults 1 Tablespoonful 15 c. c. Instructions: Take at night on retiring. If desired result is not produced by morning, the dose may be repeated." Examination of the article indicated that it possessed essentially the composition stated upon its label. It was alleged to be misbranded in that, by reason of its content of Chenopodium oil, it was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling. It was alleged to be misbranded further in that the following statements appearing in the circular entitled "Kemp's Vermifuge" were misleading: "Usual Symptoms of The Presence of Intestinal Worms. The patient loses color and weight and his abdomen becomes swollen and hard, he complains of pains in the stomach and in the region of the navel; his appetite is capricious and he craves sweets; he scratches his nose almost continuously or grinds his teeth in his sleep." The conditions mentioned above might have been due to various causes other than the presence of intestinal worms, and they might have led to the use of the article in conditions for which it would be of no value.

On April 17, 1945, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

1452. Misbranding of Nion D Capsules. U. S. v. 6 Cases of Nion D Capsules. Default decree of condemnation and destruction. (F. D. C. No. 14424. Sample No. 73943–F.)

On November 15, 1944, the United States attorney for the District of Arizona filed a libel against 6 cases, each containing 6 cartons of 100 capsules each, of Nion D Capsules at Phoenix, Ariz., alleging that the article had been shipped on or about August 4, 1944, by the Nion Corporation, Los Angeles, Calif. The article was represented on its label as containing 50,000 U. S. P. units of vitamin D per capsule.

It was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested by its labeling, "One capsule four times a day for the first month, increasing a capsule a day per week up to ten capsules per day."

On March 20, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1453. Misbranding of Boyle Vitamin D Capsules. U. S. v. 13 Bottles of Boyle Vitamin D Capsules. Default decree of condemnation and destruction. (F. D. C. No. 14013. Sample No. 74290–F.)

On October 11, 1944, the United States attorney for the District of Arizona filed a libel against 13 100-capsule bottles of the above-mentioned product at Phoenix, Ariz., alleging that the article had been shipped on or about July 8, 1944, by Boyle and Co., Los Angeles, Calif.

Examination showed that the article contained approximately 50,000 U. S. P. units of vitamin D per capsule.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested by the labeling, namely, "One capsule 4 times a day for first month, increasing a capsule a day per week up to 10 capsules per day."

On November 21, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DECOMPOSITION OR CONTAMINATION WITH FILTH

1454. Adulteration and misbranding of Mela-Vim. U. S. v. 650 Bottles of Mela-Vim. Default decree of condemnation and destruction. (F. D. C. No. 14369. Sample No. 63930–F.)

On November 16, 1944, the United States attorney for the Southern District of Florida filed a libel against 650 bottles of Mela-Vim at Jacksonville, Fla., alleging